

PATENT
ATTORNEY DOCKET NO. 50304/128001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Bondy et al. Confirmation No.: 4926
Serial No.: 10/583,814 Art Unit: 1625
Filed: June 4, 2007 Examiner: Niloofar Rahmani
Customer No.: 21559
Title: IMIDAZO 4,5-C PYRIDINE COMPOUNDS AND METHODS OF ANTIVIRAL TREATMENT

APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705

In response to the Determination of Patent Term Adjustment under 35 U.S.C. § 154(b) transmitted on September 15, 2009 in connection with the above-captioned patent application, Applicants hereby request reconsideration of the patent term adjustment. The Determination states that if "the patent issued on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 160 day(s)." March 30, 2010 is the Tuesday failing 28 weeks after the mailing of this Determination. Applicants submit that, if the patent issues on March 30, 2010, the correct total Patent Office delay is 472 days, and therefore the total patent term adjustment should be 441 days (i.e., total Patent Office delay of 472 days minus total applicant delay of 31 days). Applicants discuss the basis for this request below.

Background Law and Rules

35 U.S.C. § 154(b)(1)(A) states:

Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the Patent and Trademark Office to-

- (i) provide at least one of the notifications under section 132 of this title or a notice of allowance under section 151 of this title not later than 14 months after-

the date on which an application was filed under section 111(a) of this title;

(ii) respond to a reply under section 132, or to an appeal taken under section 134, within 4 months after the date on which the reply was filed or the appeal was taken

* * *

the term of the patent shall be extended 1 day for each day after the end of the period specified in clause (i), (ii), (iii), or (iv), as the case may be, until the action described in such clause is taken.

Corresponding provisions are found in 37 C.F.R. §§ 1.702(a)(1)-(2) and 1.703(a)(1)-(2).

Applicants refer to Office delay under 35 U.S.C. § 154(b)(1)(A), and the corresponding rules, as “A delay.”

35 U.S.C. § 154(b)(1)(B) states:

Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application in the United States, not including-

* * *

the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued.

Corresponding provisions are found in 37 C.F.R. §§ 1.702(b) and 1.703(b). As stated in 37 C.F.R. § 1.702(b), the three year period runs from the date on which the National Stage commenced under 35 U.S.C. § 371(b). Applicants refer to Office delay under 35 U.S.C. § 154(b)(1)(B), and the corresponding rules, as “B delay.”

35 U.S.C. § 154(b)(2)(A) states (emphasis added):

To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

A corresponding provision is found in 37 C.F.R. § 1.703(f).

The Office has explained its interpretation of the “overlap” provisions of 35 U.S.C. § 154(b)(2)(A) and 37 C.F.R. § 1.703(f) as follows (emphasis added):

[T]he Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. 154(b)(1)(B), **the entire period during which the application was pending before the Office** (except for periods excluded under 35 U.S.C. 154 (b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the relevant period under 35 U.S.C. 154 (b)(1)(B) in determining whether periods of delay “overlap” under 35 U.S.C. 154(b)(2)(A).

Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A), 69 Fed. Reg. 34283, 34283 (Jun. 21, 2004). However, the Office’s interpretation was recently rejected by the U.S. District Court for the District of Columbia, which stated (emphasis added):

The operative question under 35 U.S.C. § 154(b)(2)(A) is whether “periods of delay attributable to grounds specified in paragraph (1) overlap.” The only way that periods of time can “overlap” is if they occur on the same day. If an “A delay” occurs on one calendar day and a “B delay” occurs on another, they do not overlap, and § 154(b)(2)(A) does not limit the extension to one day. Recognizing this, the PTO defends its interpretation as essentially running the “period of delay” under sub-section (B) from the filing date of the patent application, such that a period of “B delay” always overlaps with any periods of “A delay” for the purposes of applying § 154(b)(2)(A).

The problem with the PTO’s construction is that it considers the application delayed under § 154(b)(1)(B) during the period before it has been delayed. That construction cannot be squared with the language of § 154(b)(1)(B), which applies “if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years.” (Emphasis added.) “B delay” begins when the PTO has failed to issue a patent within three years, not before.

Wyeth v. Dudas, No. 07-1492 (JR), 2008 U.S. Dist. LEXIS 76063, at *3 (D.D.C. Sept. 30, 2008).

Accordingly, Applicants submit that, where A delay occurs entirely before the three-year date, and thus does not overlap the period of B delay, the periods of A delay and B delay are not

to be considered overlapping under § 154(b)(2)(A), but rather must be added together to determine the overall Office delay.

The Present Application

The present application commenced the National Stage under 35 U.S.C. § 371(b) on June 22, 2006, and the period for Patent Office B delay began on June 23, 2009 and runs until the patent issues. The total Patent Office B delay until March 30, 2010 is thus 281 days. The Patent Office previously accounted for a delay of 191 days for mailing a Non-Final Rejection on February 11, 2009, none of which overlaps with the period between June 23, 2009 and the issue date.

Applicants submit that the Patent Office A delay under 35 U.S.C. § 154(b)(1)(A) was correctly calculated as 191 days.

Likewise, based on an analysis of 37 C.F.R. § 1.704, Applicants agree with the Office's calculation that the total applicant delay is 31 days.

Consistent with *Wyeth*, as the Patent Office A delay under 35 U.S.C. § 154(b)(1)(A) of 191 days and the anticipated Patent Office B delay under 35 U.S.C. § 154(b)(1)(B) of 281 days do not encompass overlapping calendar days, they should be added to provide a total Patent Office delay of 472 days. *Id.*

Applicants submit that the correct total Patent Term Adjustment should be 441 days (472 days of total Patent Office delay - 31 days of total Applicant delay = 441 days), and such correction is also hereby respectfully requested.

Applicants are aware that the total B delay cannot be calculated until the issue date for the patent has been determined. This Application is filed to preserve Applicants rights as the Determination mailed on September 15, 2009 does not acknowledge that any future calculation regarding B delay will be made.

CONCLUSION

For the above reasons, Applicants submit that the current patent term adjustment should be 441 days and request reconsideration of the patent term adjustment. The present patent is not subject to a terminal disclaimer.

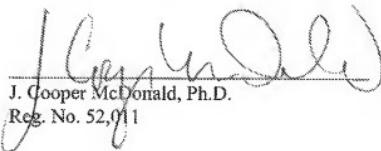
The fee set forth in 37 C.F.R. § 1.18(e) is transmitted herewith. If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date:

10/1/09

J. Cooper McDonald, Ph.D.
Reg. No. 52,011



Clark & Elbing LLP
101 Federal Street
Boston, MA 02110
Telephone: 617-428-0200
Facsimile: 617-428-7045